No. 05- 1006

IN THE

Supreme Court of the United States

APOTEX INC. AND APOTEX CORP.,

Petitioners,

v.

PFIZER INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

SUPPLEMENTAL BRIEF FOR RESPONDENT

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of this Court's rules, respondent Pfizer Inc. ("Pfizer") states that it has no parent and no publicly held company owns 10% or more of its stock.

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SUPPLEMENTAL BRIEF FOR RESPONDENT

Pfizer submits this supplemental brief pursuant to Rule 16.8 of this Court's rules to inform the Court of factual developments occurring after Pfizer filed its opposition that have rendered the case moot.

STATEMENT OF THE CASE

Two intervening developments have eliminated any arguable present or future controversy between the parties about the patent that is the subject of this declaratory judgment action.

First, on August 10, 2006, Pfizer sent to counsel for Apotex an unconditional covenant not to sue Apotex with respect to that patent, United States Patent No. 5,248,699 (the "'699 patent"). *See* Addendum at 1a-2a. This covenant ensures that Apotex will never face any risk of a lawsuit by Pfizer under the subject patent.

Second, on August 14, 2006, Teva Pharmaceutical Industries Ltd. ("Teva"), the successor to Ivax Pharmaceuticals, Inc., publicly announced that it had begun marketing its generic version of Zoloft®. *See* Addendum at 3a-5a. Under the statutory regime applicable to this case (which has been amended for future cases, *see* Opp. at 3-5), Teva's marketing started the 180-day exclusivity period that Apotex sought to trigger with a hypothetical court judgment in its favor. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Therefore, any future court judgment regarding the '699 patent would no longer have any effect on the exclusivity period.

Because of these developments, counsel for Pfizer suggested to Apotex that the case is moot and requested that Apotex withdraw its petition for a writ of certiorari. However, on August 18, 2006, counsel for Apotex replied that it did not consider the case moot and that it would not withdraw the petition. Apotex did not explain how any issue

in the case could survive the intervening developments described above.

SUPPLEMENTAL REASONS FOR DENYING THE PETITION

A case becomes moot if the plaintiff "no longer has a legally cognizable interest in the outcome." *City News & Novelty, Inc. v. City of Waukesha*, 531 U.S. 278, 283 (2001) (internal quotation marks omitted). Thus, where a complaining party has "received the full relief he requested," *Clayton v. Int'l Union, United Auto., Aero., & Agric. Implement Workers of Am.*, 451 U.S. 679, 692 (1981), there remains no constitutional case or controversy between the parties and the action becomes moot. In particular, a declaratory judgment action becomes moot when the relief requested by the plaintiff has become unnecessary because the underlying alleged injury has been removed or the relief sought from the court has already been provided. *See, e.g.*, *Golden v. Zwickler*, 394 U.S. 103, 109-10 (1969) (declaratory judgment action to adjudicate right to distribute literature opposing Congressman moot where Congressman became a judge); *Taylor v. McElroy*, 360 U.S. 709, 710-11 (1959) (per curiam) (action seeking declaratory and injunctive relief based on denial of security clearance mooted by issuance of clearance and guarantee against revocation based on subject grounds).

In this case, Apotex seeks to adjudicate whether a potential future generic drug contemplated by Apotex would infringe the '699 patent, and whether the '699 patent is valid. In light of Pfizer's covenant not to sue Apotex with respect to the '699 patent, Apotex no longer faces any risk of a lawsuit under that patent, thus eliminating any interest Apotex might have had in adjudicating either the patent's infringement or its validity. The covenant not to sue effectively gives Apotex the full relief that a court could provide in this action. Indeed, Apotex argued below that there was a cognizable dispute because Pfizer had *not* "given

Apotex a covenant not to sue." Brief for Plaintiffs-Appellants Apotex Inc. and Apotex Corp., No. 05-1199, at 19 (Fed. Cir. Mar. 22, 2005); *see also id.* at 41-42. Now that Apotex has received such a covenant, there is no potential present or future adversity between the parties about the '699 patent. The case is thus legally moot.

Apotex has argued that, apart from any threat of suit by Pfizer on the '699 patent, Apotex is harmed by its inability to use a hypothetical future court judgment in its favor to start the 180-day statutory exclusivity period in favor of Teva. As Pfizer explained in its opposition (at 21-24), this purported collateral "injury" could not properly sustain a declaratory judgment action against Pfizer regarding the '699 patent. But, in any event, any such issue is now also moot due to the intervening fact of Teva's marketing its generic product. Under the pre-amendments statutory regime applicable to this case, the exclusivity clock begins running with the earlier of Teva's marketing or a court judgment of non-infringement or invalidity. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Now that Teva's marketing has already started the 180-day clock, no court judgment could have any effect on the exclusivity analysis, even if Apotex could obtain such a judgment before the 180-day period ended. Thus, even Apotex's non-justiciable interest in this case is legally moot.

Nor does this case fall within the exception to the mootness doctrine for issues that are capable of repetition yet evading review. That doctrine "applies only in exceptional situations." *City of Los Angeles v. Lyons*, 461 U.S. 95, 109 (1983). Specifically, in order for that narrow exception to apply, (1) the challenged action must be too short in duration "to be fully litigated prior to cessation or expiration," and (2) there must be a reasonable expectation that the same plaintiff will face the same issue again in the future. *Spencer v. Kemna*, 523 U.S. 1, 17 (1998). Neither of these requirements is even arguably satisfied here.

As to the durational requirement, this is not a case where there is some intrinsic reason why any future litigation over the same issue would be too short to allow judicial resolution of the issue, for example, because the underlying issue involves an inherently transitory condition, *see Roe v. Wade*, 410 U.S. 113 (1973), or because disputes of the kind at issue "typically are resolved quickly by executive or legislative action," *Burlington N. R.R. Co. v. B'hood of Maintenance of Way Employes*, 481 U.S. 429, 436 n.4 (1987). To the contrary, when Pfizer litigated the very same legal issue involving the same patent at issue here against another generic drug manufacturer, the case proceeded through final judgment, appeal, and Supreme Court review without the case becoming moot. *See Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir.), *reh'g denied*, 405 F.3d 990 (Fed. Cir.), *cert. denied*, 126 S. Ct. 473 (2005).

Nor is Apotex likely to face the same issue again in the future, *Spencer*, 523 U.S. at 17. In the first place, as shown in Pfizer's opposition (at 11-14), there is little likelihood that the patent issues to be adjudicated in this declaratory judgment action would recur, both because the statutory scheme has been fundamentally altered for future cases, and because the issues here are highly fact-bound. Moreover, given Pfizer's covenant not to sue, there is no chance of recurrence, because the issues in this case are whether an Apotex product would infringe the '699 patent, and whether that patent is valid. Now that Apotex has received an enforceable guarantee that it will never be sued on that patent, Apotex will assuredly never need to litigate those issues again in the future. *See, e.g., Deakins v. Monaghan*, 484 U.S. 193, 199-201 (1988) (respondent's commitment not to seek equitable relief precluded its reassertion and rendered the capable of repetition yet evading review exception unavailable). More generally, Apotex could not satisfy this prong of the "capable of repetition yet evading review" exception even with respect to the broader question of whether similar disputes involving different patents might

recur in the future. Patent rights are valuable and patentees do not lightly or frequently relinquish them. Thus, there is little reason to assume that Apotex will again face a situation where its desire to litigate validity and/or infringement issues will be mooted by issuance of a covenant not to sue, as innovators will not usually be willing to abandon valuable intellectual property rights.

As an illustration, in this case, the subject patent is not even the primary patent protecting Zoloft®; the subject patent merely claims one particular form of the active ingredient in Zoloft®. Thus, Pfizer was not willing to waive its rights on the '699 patent in the earlier *Teva* litigation, because the principal patent claiming that active ingredient was still viable and enforceable. However, once the basic patent expired, Ivax's ANDA was approved immediately, and the value of the '699 patent was transferred to Ivax by virtue of its license from Pfizer; after that, no lawsuit on the '699 patent could operate to maintain exclusivity for the Zoloft® brand. Once Teva's generic product entered the market, Pfizer lost any commercial interest in asserting the '699 patent. In short, Pfizer's decision to grant a covenant not to sue in this case is no basis for Apotex contending that it will be denied the opportunity in other cases to litigate validity and infringement issues.

In sum, the fact that Pfizer has given Apotex a covenant not to sue moots the case. Even a mere voluntary cessation of conduct can moot a case. *See, e.g.*, *County of Los Angeles v. Davis*, 440 U.S. 625, 631 (1979). While the potential for reinstitution of conduct voluntarily ceased sometimes keeps a case alive, an enforceable relinquishment of rights fully moots a dispute. *See, e.g.*, *Deakins*, 484 U.S. at 200-01. And, under this Court's cases, the mere "potential for manipulation" by repeating mootness-inducing conduct in future cases does not itself justify application of the exception. *Id.* at 200-01 & n.5 (potential reassertion in future case insufficient to avoid mootness). Indeed, the significant financial costs of forfeiting valuable patent rights

prevent any realistic possibility that covenants not to sue could be used as a systematic tool to manipulate the jurisdiction of the federal courts.

CONCLUSION

The petition for a writ of certiorari should be denied, or dismissed as moot.

Respectfully submitted,

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APPENDIX

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COVENANT

WHEREAS, Pfizer Inc. ("Pfizer") owns all right, title and interest in and to United States Patent No. 5,248,699 ("the '699 patent"); and

WHEREAS Apotex Inc. and Apotex Corp. (together "Apotex") filed in the United States District Court for the Southern District of New York a civil action against Pfizer, Civil Action No. 04-CV-02539 (DC), in which Apotex sought a declaratory judgment that, inter alia, "the manufacture, sale, offer for sale, use, or importation of Apotex's proposed generic sertraline hydrochloride drug produce, that is the subject of ANDA No. 76-882, does not and will not infringe . . . any valid or enforceable claim of the '699 patent";

WHEREAS the civil action brought by Apotex was dismissed upon motion by Pfizer, and the dismissal of

Apotex's civil action was affirmed upon appeal to the United States Court of Appeals for the Federal Circuit;

WHEREAS Pfizer Inc., to avoid still further litigation with Apotex, will grant Apotex a covenant not to sue with respect to the '699 patent;

NOW THEREFORE, Pfizer hereby states as follows:

1. Pfizer unconditionally agrees, promises and covenants that Pfizer will not sue or otherwise enforce the '699 patent against Apotex in connection with the manufacture, sale, offer for sale, use, or importation of Apotex's proposed generic sertraline hydrochloride drug product, that is the subject of ANDA No. 76-882.

2. This covenant shall not be construed as a license, implied or otherwise, to any claim of any other patent, or any other claim or patent owned by or licensed to Pfizer, now or in the future. This covenant does not constitute an admission by Pfizer that the claims of the '699 patent are invalid or not infringed by Apotex in connection with the manufacture, sale, offer for sale, use, or importation of Apotex's proposed generic sertraline hydrochloride drug product, that is the subject of ANDA No. 76-882.

3. This covenant shall be binding upon and inure to the benefit of the parties and their respective successors-in-interest.

Dated: August 9, 2006 By: [signed]
Peter C. Richardson
Senior Vice President and
Associate General Counsel
Pfizer Inc.

Press Release

Teva Announces Launch of Generic Zoloft®

Jerusalem, Israel, August 14, 2006 — Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) announced today that it has begun the sale of its generic version of Pfizer's Zoloft® (Sertraline) Tablets, 25 mg, 50 mg, and 100 mg in the United States. As the first company to file an ANDA containing a paragraph IV certification for this product, Teva has been awarded a 180-day period of marketing exclusivity.

Teva's AB-rated Sertraline Tablets are indicated for treatment of major depressive disorder. Annual brand product sales in the U.S. were approximately $3.1 billion for the twelve months ended June 2006, based on IMS data.

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 20 pharmaceutical companies in the world and is the leading generic pharmaceutical company. The company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients, as well as animal health pharmaceutical products. Over 80% of Teva's sales are in North America and Europe.

Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995: This release contains forward-looking statements, which express the current beliefs and expectations of management. Such statements are based on management's current beliefs and expectations and involve a number of known and unknown risks and uncertainties that could cause Teva's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks

relating to Teva's ability to rapidly integrate Ivax Corporation's operations and achieve expected synergies, Teva's ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competing generic products, the impact of competition from brand-name companies that sell or license their own brand products under generic trade dress and at generic prices (so called "authorized generics") or seek to delay the introduction of generic product, the impact of consolidation of our distributors and customers, regulatory changes that may prevent Teva from exploiting exclusivity periods, potential liability for sales of generic products prior to a final resolution of outstanding litigation, including that relating to the generic versions of Allegra®, Neurontin®, Oxycontin® and Zithromax®, the effects of competition on Copaxone® sales, including as a result of the expected reintroduction of Tysabri® into the market, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority approvals, the regulatory environment and changes in the health policies and structures of various countries, Teva's ability to successfully identify, consummate and integrate acquisitions, potential exposure to product liability claims, dependence on patent and other protections for innovative products, significant operations worldwide that may be adversely affected by terrorism or major hostilities, environmental risks, fluctuations in currency, exchange and interest rates, operating results and other factors that are discussed in Teva's Annual Report on Form 20-F and its other filings with the U.S. Securities and Exchange Commission. Forward-looking statements speak only as of the date on which they are made and the Company undertakes no obligation to update publicly or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

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